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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/917,278	07/30/2001	Reginald M. Gorczynski	9579-39	9183

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MICHELINE GRAVELLE
Bereskin & Parr
Box 401
40 King Street West
Toronto, ON M5H 3Y2
CANADA

EXAMINER	
ROARK, JESSICA H	
ART UNIT	PAPER NUMBER
1644	15

DATE MAILED: 02/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/917,278	GORCZYNSKI ET AL.	
	Examiner	Art Unit	
	Jessica H. Roark	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) *4-9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 October 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *9,13* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 1-9 are pending.

2. Applicant's election of Group I (claims 1-3) in Paper No. 14 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 4-9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Claims 1-3 *are under consideration in the instant application.*

Specification

3. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention *to which the claims are directed.*

It is suggested that Applicant amend the title to read -- METHODS OF TREATING CANCER BY ADMINISTERING ANTIBODIES TO OX-2 --.

Priority

5. Applicant is reminded to amend the first line of the specification to reflect that USSN 09/570,367 is now U.S. Pat. No. 6,338,851.

6. Applicant's claim for domestic priority under 35 U.S.C. 119(e) and 35 U.S.C. 120 is acknowledged.

However, while it appears that all priority documents provide adequate written support for a method of treating cancer; the instant claim language does not appear to have adequate written support in any of the priority documents. The instant claims are broader in scope than a method of treating cancer, encompassing any in vivo or in vitro inhibition or reduction of tumor cell growth.

Should Applicant disagree with the Examiner's factual determination above, it is incumbent upon Applicant to provide a showing that specifically supports the instant claim limitations.

7. It is acknowledged that OX-2 proteins from at least human, mouse and rat were known in the art at the time the invention was made, as set forth in Figures 7 and 8 and discussed on page 19 of the instant specification

8. Applicant's election with respect to a method involving administration of an antibody to OX-2 in Paper No. 14 is again acknowledged. The following rejections under 35 USC 112, first paragraph, are set forth with respect to the full breadth of the instant claims as currently recited.

Claim Rejections - 35 USC § 112 first paragraph

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1-2 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The following *written description* rejection is set forth herein.

The claims recite an "agent that inhibits an OX-2 protein" as part of the invention.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. (See Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, especially page 1106 3rd column). A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. MPEP 2163 II.A.3a.ii.

Claims 1 recites a method utilizing any "agent" which inhibits an OX-2 protein without providing a physical structure for the "agent". The genus of "agents" is therefore extremely large. Applicant has disclosed only antibodies to OX-2 and nucleic acids which are "agents" that inhibit an OX-2 protein and have a defined structure. Claim 2 requires the agent bind OX-2. However, Applicant has disclosed only antibodies which bind OX-2 and inhibit the OX-2 protein. Thus Applicant has disclosed only a limited number of "agents". These "agents" lack a common structure essential for their function and the claims do not require any particular structure be shared by the instant "agents". It does not appear based upon the limited disclosure that Applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the limited number of species disclosed and the extensive variation permitted within the genus of "agents".

Consequently, Applicant was not in possession of the instant claimed invention. See Regents of the University of California v. Eli Lilly and Co. 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). Adequate written description of genetic material "'requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention." Id. 43 USPQ2d at 1404 (quoting Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606). The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter of the claim. Id. 43 USPQ2d at 1406. A description of what the genetic material does, rather than of what it is, does not suffice. Id.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Applicant is invited to point to clear support or specific examples of the claimed invention in the specification as-filed.

11. Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method or inhibiting or reducing tumor cell growth by administering an antibody to OX-2, does not reasonably provide enablement for:

a) a method of *preventing* tumor cell growth, or

b) a method of inhibiting or reducing tumor cell growth by administering *any agent that inhibits OX-2*.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

a) "Preventing tumor cell growth":

The instant claims are drawn to a method that prevents tumor cell growth. Reasonable guidance with respect to preventing any cancer relies on quantitative analysis from defined populations which have been successfully pre-screened and are predisposed to particular types of cancer. This type of data might be derived from widespread genetic analysis, cancer clusters, or family histories. The essential element towards the validation of a preventive therapeutic is the ability to test the drug on subjects monitored in advance of clinical cancer and *link* those results with subsequent histological confirmation of the presence or absence of disease. This irrefutable link between antecedent drug and subsequent knowledge of the prevention of the disease is the essence of a valid preventive agent.

While various antibody-based therapeutics have shown some promising efficacy in the therapy of cancer, a recent review of such therapies by Pardoll (Clin. Immunol. 2000; 95(1):S44-S62) did not indicate nor suggest that such therapies would be successful in the prevention of cancer. Although Applicant has similarly shown therapeutic efficacy in certain in vivo models of cancer/tumor cell growth following tumor cell challenge; there does not appear to be sufficient guidance in the specification as filed as to how the skilled artisan can identify those at risk of developing various cancers and prevent the growth of tumor cells in those individuals.

Without detailed guidance with respect to pre-screening methods or other means of identifying those individual to whom an antibody to OX-2 should be administered prior to the initial growth of tumor cells, it would require undue experimentation of the skilled artisan to practice a method of preventing tumor cell growth.

b) "Agents":

Instant claims 1 and 2 recite "an agent that inhibits" an OX-2 protein (claim 1), including "agents which bind" an OX-2 protein. The specification discloses antibodies that bind OX-2 and inhibit the function of OX-2 (e.g., the Examples on pages 68-74, 83-85 and 91-92 of the specification) and can be used in methods of inhibiting or reducing tumor cell growth. The specification also discloses that other "agents" which inhibit OX-2 may be identified by screening (e.g., specification pages 9-10).

However, there appears to be insufficient guidance in the specification as filed to allow one skilled in the art to conduct such screening with a reasonable expectation of success. Applicant does not appear to provide any working examples with respect to inhibitors other than antibodies. In addition, the state of the art at the time the invention was made did not appear to recognize any "agents" that bound OX-2 other than antibodies.

The skilled artisan was well aware that, in general, the design/identification of binding agents was highly unpredictable, especially in the absence of a lead compound. For example, Huang (Pharmacol. Therapeutics 2000 86:201-215) reviews in his "Introduction" on page 202 the daunting task faced by the skilled artisan in developing small molecule regulators of protein-protein interactions, and notes that the process required long periods of trial and error testing before suitable compounds could be developed.

Thus in view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification, and the breadth of the claims, it would require undue experimentation to practice the claimed invention as broadly claimed with respect to methods of inhibiting or reducing tumor cell growth with any "agent that inhibits" or "agent that binds" an OX-2 protein other than an antibody to OX-2.

35 U.S.C. § 102

12. The following rejections are set forth assuming the effective filing date of the instant claims is 7/30/2001, for the reasons set forth supra in the discussion regarding adequate written support in the priority documents.

Amendment of the claims to recite claim language for which there is adequate written support in the priority documents would obviate these rejections.

13. The following rejections are set forth with respect to the enabled embodiment of a method of inhibiting or reducing tumor cell growth by administering an antibody to OX-2.

Claim Rejections – 35 U.S.C. § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

15. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Gorczynski (WO 99/24565, IDS, see entire document).

Gorczynski teaches a method of treating cancer by administering an antibody to OX-2 (see entire document, but especially page 9 at lines 3-24).

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention.

A method of treating cancer inherently requires inhibiting or reducing tumor cell growth in vivo; therefore the reference teachings anticipate the instant claimed invention.

16. Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by Gorczynski (U.S. Pat. No. 6,338,851, see entire document).

Gorczynski teaches a method of treating cancer by administering an antibody to OX-2 (see entire document, but especially column 7 at line 49 to column 8 at line 11).

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention.

A method of treating cancer inherently requires inhibiting or reducing tumor cell growth in vivo; therefore the reference teachings anticipate the instant claimed invention.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Conclusion

17. No claim is allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica Roark, whose telephone number is (703) 605-1209. The examiner can normally be reached Monday to Friday from 8:00 to 4:30. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Jessica Roark, Ph.D.
Patent Examiner
Technology Center 1600
February 21, 2003

PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER
TECH CENTER 1600
2/21/03